510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name:

Toshiba America Medical Systems, Inc.

Address:

PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068

Contact:

Paul Biggins, Director Regulatory Affairs

Telephone No.:

(714) 730-5000

Device Proprietary Name: SSA-790A, Aplio XG Version 3.0

AUG 1 2 2008

Common Name:

Diagnostic Ultrasound System

Classification:

Regulatory Class: II Review Category: Tier II

- Ultrasonic Pulsed Doppler Imaging System Product Code: 90-IYN [Fed. Reg. No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System Product Code: 90-IYO [Fed. Reg. No.: 892.1560]
- Diagnostic Ultrasonic Transducer Product Code: 90-ITX [Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

- 1. Toshiba SSA-790A, Aplio XG Version 2.2 Diagnostic Ultrasound; 510(k) K081065
- 2. Hitachi Medical Systems America Inc. HI VISION 900 Diagnostic Ultrasound Scanner 510(k) K063518

Device Description:

The Aplio XG Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:

The Aplio XG is intended to be used for the following types of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-2 (applicable portion), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

SEP 9 - 2008

Toshiba America Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K082119

Trade/Device Name: Aplio XG v3.0 SSA-790A

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 26, 2008 Received: July 28, 2008

Dear Mr. Job:

This letter corrects our substantially equivalent letter of August 12, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the <u>Aplio XG v3.0 SSA-790A</u>, as described in your premarket notification:

Transducer Model Number

<u>PVT-375BT</u>	<u>PET-510MB</u>
PVT-661VT	<u>PST-25BT</u>
PLT-1202S	<u>PLT-604AT</u>
<u>PC-20M</u>	<u>PLT-704AT</u>

<u>PLT-805AT</u>	<u>PLT-1204MV</u>
PLT-1204AT	PVT-382MV
PLT-1204AX	<u>PVT-681MV</u>
<u>PVT-382BT</u>	<u>PET-511BTM</u>
<u>PVT-674BT</u>	<u>PC-50M</u>
<u>PVT-575MV</u>	<u>PLT-705BTF</u>
<u>PVT-770RT</u>	<u>PLT-705BTH</u>
PST-30BT	<u>PLT-1204BT</u>
PST-50AT	<u>PLT-1204BX</u>
PST-65AT	<u>PVT-745BTV</u>
PLT-704SBT	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to

proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Joyce M. Whang, Ph.D.

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use Form

System Transducer X	
510(k) Number(s)	

	Mode of Operation											
Clinical Application	В	тні	M	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	P	P	P	P	P	P		P				P
Abdominal	1											
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac				·							_	· .
Transesophageal						_						
Transrectal			1									
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	1											
Laparoscopic												
Musculo-skeletal Superficial										į		
Musculo-skeletal	\top											
Conventional				1				1		1		

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BD	PF/MDF/PWD	
Previous 510(k	s) for this device K081065	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number __

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System Transduce	X		
Model PVT-770RT			
510(k) Number(s)	- 	The state of the s	

	Mode of Operation									_		
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	Ī											
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	1											
Small Organ (Specify)*												
Neonatal Cephalic											_	
Adult Cephalic												
Cardiac												
Transesophageal					,							
Transrectal	· P	P	P	P	P	P		P				P
Transvaginal												
Transurethral			1					1				
Intravascular		1	1									
Peripheral Vascular			T									
Laparoscopic	1	•										
Musculo-skeletal			Ti									
Superficial												
Musculo-skeletal										1		
Conventional		1		[ĺ		1		

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF;	BDF/MDF/PWD	
Previous :	10(k) for this device K081065	
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Radiological Devices,

Diagnostic Ultrasound Indications For Use Forms Se

System Transdi	icer X	
Model PST-30BT	१८५५ - जनसङ्ग्रह्मा	CALCADA Annual
510(k) Number(s)		

	Mode of Operation											
Clinical Application	В	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	P	P	P	P			P
Intraoperative (Specify)												
Intraoperative Neurological	ì											
Pediatric	P	P	P	P	P	P	P	P	P			P
Small Organ (Specify)*												
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			P
Adult Cephalic	P	P	P	P	P	P	P	P	P			P
Cardiac	P	P	P	P	P	P	P	P	P	P		P
Transesophageal												
Transrectal								•				,
Transvaginal								-				
Transurethral												
Intravascular	Ţ.					•						
Peripheral Vascular		1										
Laparoscopic			1								**	
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF;	BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	
CHI/2D; FEI/2D; CHI/	BDF; FEI/BDF	
Previous !	510(k) for this device K081065	

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Radiological Devices

510(k) Number _

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System Transducer X			
System Transducer X Model PST-50AT 510(k) Number(s)	and the confidence of	Henromorphy Henry (1881)	M. 484m, Signandary, Inches
510(k) Number(s)			
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	Mode of Operation											
Clinical Application	В	THI	М	Color Doppier	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic									•			
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P			P	P	P			P
Small Organ (Specify)*												
Neonatal Cephalic	P	P	P	P			P	P	P			P
Adult Cephalic												
Cardiac	P	P	P	P			P	P	P			P
Transesophageal												
Transrectal	1.											
Transvaginal	Ť											
Transurethral												
Intravascular												
Peripheral Vascular	1											
Laparoscopic												
Musculo-skeletal										T		
Superficial												
Musculo-skeletal												
Conventional								İ		Ш		

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

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Radiological Devices

510(k) Number __K082119

Diagnostic Ultrasound Indications For Use Form

System Transducer' Model PST-65AT	a madestropeas Anterior apricas	a parti kustan Perentan	
510(k) Number(s)	* *		

	Mode of Operation											
Clinical Application	В	THI	м	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic											-	
Fetal												
Abdominal											_	
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P			P	P	P			P
Small Organ (Specify)*					<u> </u>							
Neonatal Cephalic	P	P	P	P			P	P	P			P
Adult Cephalic												
Cardiac	P	P	P	P			P	P	P			P
Transesophageal												
Transrectal												
Transvaginal			Ţ				1	1				
Transurethral												
Intravascular			T									
Peripheral Vascular	7											
Laparoscopic												
Musculo-skeletal					1							
Superficial						L					L	
Musculo-skeletal												
Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF	
Previous 510(k) for this device K081065	

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Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

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510(k) Number(s)					1,3		ua mpath Na Alba Arena

	Mode of Operation											
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)										***************************************		
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*	P	P	P	P	P	P		P				P
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal] ·	
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P	P	P	P		P				P
Laparoscopic												
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;		
BDF/PWD; BDF/MDF; BD	F/MDF/PWD		
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Previous 510(k	for this device K081065		
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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and

K082119

Radiological Devices

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System Trans Model PLT 204	THE TREE T	<u> X</u>	
510(k) Number(s)		,	27.794.
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	Mode of Operation											
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal				·								
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	T		1"									
Small Organ (Specify)*	P	P	P	P	P	P		P				P
Neonatal Cephalic												
Adult Cephalic				-								
Cardiac										1		
Transesophageal												
Transrectal	1											
Transvaginal												
Transurethra!												
Intravascular				-								
Peripheral Vascular	P	P	P	P	P	P		P				P
Laparoscopic			1 -									
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BD	PF/MDF/PWD	
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number ____

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System Transduce Model PVT-382MV	ST	X		
510(k) Number(s)		,	:7	

						Mode	of Op	perati	on		·	
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	P	P	P	P	P	P		P	_			P
Abdominal	P	P	P	P	P	P		P				P
Intraoperative (Specify)		_		•								
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P		P				P
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal	T											
Transrectal			1									
Transvaginal	1									 -		
Transurethral	1											
Intravascular												
Peripheral Vascular								1				
Laparoscopic												
Musculo-skeletal							1					
Superficial	4—		\perp				-		+	+		
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BI	DF/MDF/PWD	
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices K082119

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System Transchi		HEREN STATE	
Model PVT-681MV	cer X		
510(k) Number(s)	The second secon	render i State (1985)	

						Mode	of Op	perati	on			
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal				<u> </u>								
Intraoperative (Specify)												
Intraoperative Neurological										·		
Pediatric												
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic	1											
Cardiac												
Transesophageal												1
Transrectal	P	P	P	P	P	P		P				P
Transvaginal	P	P	P	P	P	P		P	1			P
Transurethral												
Intravascular	1		1					<u> </u>				
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal	1											
Superficial									_			
Musculo-skeletal			1									
Conventional	1				1							

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BD	F/MDF/PWD	
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Previous 510(k)	for this device K081065	•
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Diagnostic Ultrasound Indications For Use Form

						Mode	of O	erati	on			•
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic			1								1.0	:
Fetal					İ							
Abdominal			1 1									
Intraoperative (Specify)	 							-				
Intraoperative Neurological												
Pediatric						_	1	1				
Small Organ (Specify)*	1											
Neonatal Cephalic								İ				
Adult Cephalic								-				
Cardiac												
Transesophageal	P	P	P	P			P	P	P			P
Transrectal		T					T					1
Transvaginal												
Transurethra!												
Intravascular												
Peripheral Vascular	1		1									
Laparoscopic												
Musculo-skeletal			·									
Superficial				<u></u>								
Musculo-skeletal												
Conventional												

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Concurrence of CDRH, Office of Device Evaluation (ODF)

Prescription Use (Per 21 CFR 801.109)

Previous 510(k) for this device K081065

(Division Sign-off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

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		DO	CON	# Gun	4.5		-4- WY6.		1114 - 7		4	4.	4			-74- · · · · · · · · · · · · · · · · · · ·	43.150	Lat Pe		12:412	化数域数		43.2 G	- (1)
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						Mode	of O	perati	on	,		
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric									P			
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac									P		_	
Transesophageal				1].							
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	Γ								P			
Laparoscopic												
Musculo-skeletal Superficial												-
Musculo-skeletal Conventional												

Additional Comments:

Previous 510(k) for this device k081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Diagnostic Ultrasound Indications For Use Form

						Mode	of O	erati	on			
Clinical Application	В	тні	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic			 									
Fetal	\vdash		1				_					_
Abdominal	N	N	N	N	N	N		N				N
Intraoperative (Specify)	N	N	N	N	N	N		N				N
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*	N	N	N	N	N	N		N				N
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular			1									
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial												
Musculo-skeletal												
Conventional						DA; E =						

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Diagnostic Ultrasound Indications For Use Form

				_		Mode	of O	2224				
Clinical Application	В	тні	М	Color Doppler	Power	Mode Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	N		N				N
Intraoperative (Specify)	N	N	N	N	N	N		N				N
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*	N	N	N	N	N	N		N				N
Neonatal Cephalic												
Adult Cephalic												
Cardiac		ĺ										
Transesophageal												
Transrectal						1						
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic		Ì										
Musculo-skeletal												
Superficial												
Musculo-skeletal			-	1								

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Prescription Use (Per 21 CFR 801.102)

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Division of Reproductive, Abdominal and

Radiological Devices

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Mode	l PLT-12	04BT	por appear of the same	المام المام المام المام المام المام المام المام المام المام المام المام المام المام المام المام المام المام ا
510(k) Number(s)	Benierbieber den die	- en en en en en en en en en en en en en	

						Mode	of Op	perati	on			
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												<u> </u>
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*	N	N	N	N	N	N	N	N				N
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal											•	
Transvaginal												
Transurethral	Ţ									-		
Intravascular	1											
Peripheral Vascular	N	N	N	N	N	N	N	N				N
Laparoscopic					1				\top			
Musculo-skeletal Superficial	N	N	N	N	N	· N	N	N				N
Musculo-skeletal Conventional	N	N	N	N	N	N	N	N				N

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: _	Combined Modes: B/M; B/P	WD;
BDF/PWD; BDF/MDF; B	BDF/MDF/PWD	

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Concurrence of CDRH, Office of Device Evaluation (QDE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Diagnostic Ultrasound Indications For Use Form

System	X Transducer
Model	Aplio XG v3.0 SSA-790A
510(k) N	lumber(s)

						Mode	of O	perati	on			
Clinical Application	В	THI	м	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	P	P	P	P	P	P		P				P
Abdominal	P	P	P	P	P	P		P	P			P
Intraoperative (Specify)	P	P	P	P	P			P				P
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P			P
Small Organ (Specify)*	P	P	P	P	P	N	N	P		'		P
Neonatal Cephalic	P	P	1	P	P	P		P	P			P
Adult Cephalic	P	P	P	P	P	P	1	P	P		1	P
Cardiac	P	P	P	P	P	P	P	P	P	P		P
Transesophageal	P	P	P	P			P	P	P			P
Transrectal	P	P	P	P	P	P		P		1		P
Transvaginal	P	P	P	P	P	P		P				P
Transurethral			T						1			
Intravascular			Ţ				-	1				
Peripheral Vascular	P	P	P	P	P	N	N	P	P			P
Laparoscopic			1					7				
Musculo-skeletal Superficial	P	P	P	P	P	N	N	P				P
Musculo-skeletal Conventional	P	P	P	P	P	N	N	P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
	F/MDF/PWD:B-TDI; M-TDI; 2D/CWD; BDF/CWD;	•
CHI/2D; FEI/2D; CHI/BDF	; FEI/BDF	
· · · · · · · · · · · · · · · · · · ·		
All indications were	previously reported via k081065	
·		
*: For example: thyroid, par	athyroid, breast, scrotum and penis	
		·

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Prescription Use (Per 21 CFR 801.109)11

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510(k) Number .

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Diagnostic elitrasounds noteations (con lese

System Transducer X Model PVT-375BT 510(k) Number(s)	System Transducer	Δ				
510(k) Number(s)	Model LAT-212DI	No.	The state of the s	e metalogistik in berg	en in the second of the in	
,一个大大大大大大大大大大大大大大大大大大大大大大大大大大大大大大大大大大大大	510(k) Number(s)					

											<u> </u>	
	Mode of Operation											
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	P	P	P	P	P	P		P			_	P
Abdominal	P	P	P	P	P	P		P				P
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P		P				P
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic								-				,
Cardiac								1				
Transesophageal			1					1				
Transrectal										1		
Transvaginal	T.											
Transurethral					1							
Intravascular												
Peripheral Vascular	1	T										
Laparoscopic	Τ.	Ì	7									
Musculo-skeletal Superficial												
Musculo-skeletal Conventional					•							

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;
BDF/PWD; BDF/MDF; BD	F/MDF/PWD
Previous 510(k) for this device K081065

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Prescription Use (Per 21 CFR 801.109)

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Radiological Devices

510(k) Number(s)

		Mode of Operation										
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow	ומד	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												,
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric								ļ -				
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												- - -
Cardiac										-		
Transesophageal				_								
Transrectal	P	P	P	P	P	P		P				· P
Transvaginal	P	P	P	· P	P	P		P		T		P
Transurethral												
Intravascular	Τ.		1			1						
Peripheral Vascular									1			
Laparoscopic			.]						1			
Musculo-skeletal Superficial					1							
Musculo-skeletal Conventional						 						

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWI	<u>D:</u>
BDF/PWD; BDF/MDF; B	DF/MDF/PWD	· ·
Previous 510	(k) for this device K081065	
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

System Transducer X			THE PARTY IN	
Model PLT-1202S				
510(k) Number(s)		 		
		1. 1. 1		٠.,

	Mode of Operation												
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)	
Ophthalmic													
Fetal						,							
Abdominal													
Intraoperative (Specify)	P	P	P	P	P			P				P	
Intraoperative Neurological								•					
Pediatric										•			
Small Organ (Specify)*	P	P	P	P	P			P		,		P	
Neonatal Cephalic													
Adult Cephalic													
Cardiac									,				
Transesophageal													
Transrectal		1											
Transvaginal													
Transurethral								1	1				
Intravascular			1							1			
Peripheral Vascular	P	P	P	P	P		T	P				P	
Laparoscopic													
Musculo-skeletal Superficial	P	P	P	P	P			P				P	
Musculo-skeletal Conventional	P	P	P	P	P			P				P	

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD;							
BDF/PWD; BDF/MDF; BDF	/MDF/PWD						
Previous 510(k) 1	for this device K081065						

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices
510(k) Number

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System Transduc	A CONTRACTOR OF THE PARTY OF TH	
Model PC-20M		68 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
510(k) Number(s)		
	and the second of the second o	A. 5. 5

	Mode of Operation												
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow_	Combined (Specify)	
Ophthalmic													
Fetal													
Abdominal												,	
Intraoperative (Specify)													
Intraoperative Neurological													
Pediatric									P				
Small Organ (Specify)*					1								
Neonatal Cephalic										·			
Adult Cephalic					I								
Cardiac	1								P				
Transesophageal								,					
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular									P				
Laparoscopic													
Musculo-skeletal Superficial													
Musculo-skeletal Conventional												` `	

Additional Comments:		 	
Previous 510(k) f	or this device K081065		• •

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Diagnostic Plitzsound nichteition (1901-1986) vorm System Transducer X

	Mode of Operation												
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)	
Ophthalmic				<u>. </u>									
Fetal													
Abdominal	ļ		$oxed{oxed}$					ļ	<u> </u>				
Intraoperative (Specify)								1					
Intraoperative Neurological	·				_							,	
Pediatric		<u> </u>	$oxed{oxed}$		1		<u> </u>						
Small Organ (Specify)*	<u> </u>	ļ								ļ			
Neonatal Cephalic	ļ						ļ		ļ	<u> </u>			
Adult Cephalic	<u> </u>	<u> </u>			ļ	<u> </u>	<u> </u>						
Cardiac	<u> </u>	Ļ_					ļ					ļ	
Transesophageal	P	P	P.	P			P	P	P		ļ	.Р	
Transrectal		<u> </u>				<u> </u>	<u> </u>	 	ļ	<u> </u>	· · ·		
Transvaginal	-								ļ	↓	<u> </u>		
Transurethral	╄		-		ļ	ļ			-	<u> </u>	<u> </u>	1	
Intravascular	-	-	+	ļ	 	<u> </u>				 		ļ	
Peripheral Vascular	+ -	-	+		1			+	 	 -	<u> </u>		
Laparoscopic Musculo-skeleta		ļ	_		+			 		 	 - : 	 	
Superficial										<u> </u>			
Musculo-skeletal Conventional												·	
N= new indication Additional Communication BDF/PWD; BDF	nent	s:		Combine	d Mode	s: B/M; B/	PWD:				E (LTF)		
	revio	us 510(k) for	this device k	(081065				•			-	
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						CONTINUE ON							
Prescription Use	(Per	21 C	FR 8	01.109)			Ч	الم	H				

Radiological Devices 510(k) Number ____

System I ransducer X 1951 Model PST-25BT	
510(k) Number(s)	

	Mode of Operation													
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow	TDI	₽₩	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)		
Ophthalmic			\Box		Į									
Fetal														
Abdominal	P	P	P	P	P	P	P	P	P			P		
Intraoperative (Specify)														
Intraoperative Neurological					-			1				,		
Pediatric	P	P	P	P	P.	P	P	P	P			P		
Small Organ (Specify)*	1	Ī												
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			· P		
Adult Cephalic	P	P	P	P	P	P	P	P	P			P		
Cardiac	P	P	P	P	P	P	P	P	P	. Р	<u> </u>	P		
Transesophageal	1						T				· ·			
Transrectal	†		7.						T-					
Transvaginal												, ,		
Transurethral								T .						
Intravascular	}													
Peripheral Vascular	T													
Laparoscopic	T													
Musculo-skeletal Superficial														
Musculo-skeletal Conventional									1	1				

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined in	Modes: B/M; B/PWD;		
BDF/PWD; BDF/MDF; BDF/MDF/PWD;B	-TDI; M-TDI; 2D/CW	D; BDF/CWD;	
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF			
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Previous 510(k) for this device K081	<u>065</u>	<u></u>	
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Division of Reproductive, Abdominal and Radiological Devices K082/19

Diagnostic Ultrasound Indications for Use For

System.	Tran	sducer	X	
Model	PLT-604	AT		
510(k) N	_			

Clinical Application	Mode of Operation												
	В	тні	м	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)	
Ophthalmic					·								
Fetal			1	· · ·	ĺ								
Abdominal													
Intraoperative (Specify)			, 1										
Intraoperative Neurological					_				,				
Pediatric	l												
Small Organ (Specify)*	Ρ.	P	P	P	P	P		P				P	
Neonatal Cephalic								1.					
Adult Cephalic							•						
Cardiac													
Transesophageal													
Transrectal													
Transvaginal													
Transurethral	1				1					1.		· -	
Intravascular	·					· .						, .	
Peripheral Vascular	P	P	P	P	P	P		P		1	<u> </u>	P	
Laparoscopic							T						
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P	
Musculo-skeletal Conventional	P	P	P	P	P	P	-	P				P	

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: BDF/PWD; BDF/MDF; BDF/MDF/PWD	<u>B/M; B/PWD;</u>		
		•	
Previous 510(k) for this device K981065			

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Radiological Devices

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System Transducer X Model PLT-704AT			
510(k) Number(s)	i de la compania del compania del compania de la compania del la compania de la compania de la compania de la compania de la compania de la compania del la compania del la compania de la compania del la compania d	A AN ASSAULT	

		Mode of Operation													
Clinical Application	B	THI	м	Color Doppler	Power	Dynamic Flow	וסד	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)			
Ophthalmic															
Fetal															
Abdominal															
Intraoperative (Specify)															
Intraoperative Neurological															
Pediatric						_				T					
Small Organ (Specify)*	P	P	P	P	P	P		· P				P			
Neonatal Cephalic															
Adult Cephalic			1												
Cardiac	1														
Transesophageal	1		1.												
Transrectal	1		1												
Transvaginal	1		T-							1.					
Transurethral	1		1								/				
Intravascular		-								T		· · · · · · · · · · · · · · · · · · ·			
Peripheral Vascular	P	P	P	P	P	P		P			1	P			
Laparoscopic				<u> </u>				T	1	1.					
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P			
Musculo-skeletal Conventional	P	P	P	P	P	P		P	1	1		P			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/P	WD;
BDF/PWD; BDF/MDF; BD	F/MDF/PWD	
Previous 510(k)	for this device K081065	
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510(k) Number ___

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Model	PLT-805	AΤ	La p ropinsi Carantan	77.794.
	lumber(s)			

· ·					,-	Mode	of O	erati	on			
Clinical Application	B	тні	м	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHi 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic		,										,
Fetal												_
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric											· .	
Small Organ (Specify)*	P.	P	P	_ P	Ρ	P		P				·P
Neonatal Cephalic								,				
Adult Cephalic									,			
Cardiac			-									
Transesophageal												
Transrectal												
Transvaginal											·	
Transurethral		T			1	1						
Intravascular	1										•	
Peripheral Vascular	P	P	P	P	· P	P		P				P
Laparoscopic		1	1				1.		l .			
Musculo-skeletal Superficial	P	P	P	P	P	Р .		P			:	P
Musculo-skeletal Conventional	P	P	P	P	P	Р		P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B	<u>/M; B/PWD;</u>		•
BDF/PWD; BDF/MDF; BDF	/MDF/PWD	·		·
·			-	
	•			
Previous 510(k) i	or this device K081065			

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Radiological Devices

510(k) Number ____

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System A Transducer X	and profit	15721			4
Model PLT-1204AT		1		er Williams	
510(k) Number(s)	2	, jes i res i su.	**************************************		٠,

		Mode of Operation													
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	ŤDÍ	PW	CW	·CHI 2D	CHI Dynamic Flow	Combined (Specify)			
Ophthalmic															
Fetal				•											
Abdominal]														
Intraoperative (Specify)															
Intraoperative Neurological				ı											
Pediatric						· ·									
Small Organ (Specify)*	P	P	P.	. P	P	P		P				P			
Neonatal Cephalic								Ì _			,				
Adult Cephalic															
Cardiac				·				,							
Transesophageal					-										
Transrectal															
Transvaginal			1			<u> </u>				1					
Transurethral															
Intravascular															
Peripheral Vascular	P	P	P	P	P	. P		P				P			
Laparoscopic			1									•			
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P			
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD	<u>);</u>	
BDF/PWD; BDF/MDF; BD	F/MDF/PWD		
			• • • • • • • • • • • • • • • • • • • •
		·	
Previous 510()	t) for this device K081065		

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Model PLT-1204AX
510(k) Number(s)

	Mode of Operation													
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow *	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)		
Ophthalmic												_		
Fetal		·	١.,									•		
Abdominal														
Intraoperative (Specify)												•		
Intraoperative Neurological														
Pediatric														
Small Organ (Specify)*	P	P	P	Р	P	P		P		·		P		
Neonatal Cephalic			1				1							
Adult Cephalic		_			1									
Cardiac	1		1									,		
Transesophageal									1	1				
Transrectal										1				
Transvaginal										—				
Transurethral								1		1				
Intravascular				-										
Peripheral Vascular	P	P	P	P	P	P		P		1.		P		
Laparoscopic										1				
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P		
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P		

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;		
BDF/PWD; BDF/MDF; BD	F/MDF/PWD	<u>. </u>	
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Previous 510(k) for this device K081065		

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Prescription Use (Per 21 CFR 801.109)

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Model PVT-382BT		Pera 4	1	(salay sala	4.89	56.3	a vige		rener. Kalena		11.	ij
510(k) Number(s)	. ~		•	٠				 	•			

		Mode of Operation													
Clinical Application	В	THI	м	Color Doppler	Power	Dynamic Flow	TDi	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)			
Ophthalmic															
Fetal	P	P	P	P.	P	P		P				P			
Abdominal	P	P	P	P	P	P		P				P			
Intraoperative (Specify)															
Intraoperative Neurological									1						
Pediatric	P	P	P	P	P	P		P				P			
Small Organ (Specify)*			1												
Neonatal Cephalic										1.					
Adult Cephalic		١.	1												
Cardiac									1.						
Transesophageal			1												
Transrectal			1	-							1				
Transvaginal		1								Ĭ					
Transurethral	T-	1	T-												
Intravascular		1													
Peripheral Vascular															
Laparoscopic										-					
Musculo-skeletal	· "		\top		1	1	T^-	1			,				
Superficial					<u> </u>		1					<u> </u>			
Musculo-skeletal Conventional												,			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	**	
BDF/PWD; BDF/MDF; BD	F/MDF/PWD		
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Previous 510()) for this device K081065		
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510(k) Number(s)	*	time Triberites	Marine 1	นาโดก การให้ที่ดีในสิทธิ์สูติการกระทั่งก็	We all the control	in in the second	
•			the state of	4 4 4	· .		

Clinical Application	Mode of Operation											
	В	ТНІ	м	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	P	P	P	P.	P	. Р		P			•	P
Abdominal	P	P	P	P	P	P		P				P
Intraoperative (Specify)												
Intraoperative Neurological												,
Pediatric			Ţ-									
Small Organ (Specify)*			Π.		T							
Neonatal Cephalic										1		
Adult Cephalic	1											
Cardiac			1							1		
Transesophageal			1									·
Transrectal			1						1			
Transvaginal												
Transurethral			1									
Intravascular												
Peripheral Vascular	Ţ.									1		† — —
Laparoscopic		1	1		1	-	T -			1.		
Musculo-skeletal Superficial												
Musculo-skeletal Conventional	1				1							

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: E	3/M; B/PWD;		•
BDF/PWD; BDF/MDF; BD	F/MDF/PWD			_
Previous 510(1	() for this device K081065			

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510(k) Number(s		· • • • •							٠,			
	Mode of Operation											
Clinical Application	В	ТНІ	м	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
etal												
Abdominal		-						_				
ntraoperative (Specify)			1-1	 								
ntraoperative Neurological												
Pediatric			1 1			<u> </u>				<u> </u>		
Small Organ (Specify)*	N	N	N	N	N	N	N	N	-			N
Neonatal Cephalic							<u> </u>					
Adult Cephalic												
Cardiac									1			-
Fransesophageal			T								1	
[ransrectal	T											<u> </u>
Fransvaginal	1.				<u> </u>						T	
Transurethral					1	1						T
Intravascular	1		\top		1		1					,

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Additional Comments: BDF/PWD; BDF/MDF; E		des: B/M; B/PWD;	i	
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Peripheral Vascular

Laparoscopic
Musculo-skeletal
Superficial
Musculo-skeletal
Conventional

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System 1	and the same			
Model PVT 7	45BTV		C. C. C. C. C. C. C. C. C. C. C. C. C. C	
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2 1 0 (11) 1 1 4111 0 1 (1	-,	•		

	Mode of Operation											
Clinical Application	В	тні	м	Color Doppler	Power	Dynamic Flow	TDI	рW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	N		N			,	N
Intraoperative (Specify)	N	N	N	N	N	N		N				Z
Intraoperative Neurological								,				
Pediatric												
Small Organ (Specify)*	N	N	N	N	N	N		N				N
Neonatal Cephalic						,						
Adult Cephalic												
Cardiac					1			ļ				
Transesophageal				-								
Transrectal	1		1									
Transvaginal			1					· · ·			•	
Transurethral					1							
Intravascular	T											· ·
Peripheral Vascular										1		
Laparoscopic	T_		1			T				1 -		<u> </u>
Musculo-skeletal Superficial												
Musculo-skeletal Conventional	-		-		<u>-</u>							

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	<u> combined Modes: B/M; B/PW</u>	<u>D;</u>	
BDF/PWD; BDF/MDF; BDF/MD)F/PWD		
			
			
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